510(k) Summary

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OCT 3 1 2012

Device Information

Trade Name:	Rex Anterior Cervical plate System
Common Name:	Anterior cervical plate system
Classification Name:	Spinal intervertebral body fixation orthosis
Product Code:	KWQ
Regulation Number:	888.3060
Date prepared:	10/12/2012

General Description

Rex Cervical Plate System consists of a variety of shapes and sizes of Main Plates, screw, sub-plate, rivets and the associated instruments. The sub-plate is pre-assembled to the main plate and designed to prevent screws from backing out using the elastic behavior during the screw insertion. The rivets are also pre-assembled to the main plate and designed to assemble the sub-plate to the main plate firmly. Each component is subjected to a color anodizing process to differentiate the screw type and diameter and to make the surgical process easy. The plates range in length to accommodate one, two, three, and four level procedures. Main plate are available from 20mm to 110mm. Screws are available in lengths from 10mm to 20mm in 2mm increments. The screws have either a 3.5mm or 4.0mm diameter. They are fixed self-tapping, Variable self-tapping screw, fixed self-drilling screw, Variable self-drilling and are available in lengths ranging from 10mm to 20mm in 2mm increments

The Rex Cervical Plate System components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6AI-4V ELI) that conforms to ASTM F 136.

Indication for Use

The REX Anterior Cervical Plate System is intended for anterior fixation to the cervical spine. The specific clinical indications include:

degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Performance Data:

Performance tests per ASTM F1717 such as static compression, tension, torsion, and fatigue were performed to characterize the subject Rex Cervical System components addressed in this notification.

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

*U&I corporation, Maxima ™ Anterior Cervical Plate System (K061002)

* Medtronic Sofamor Danek, VENTURE™ Anterior Cervical Plate System (K061274)

Comparison to Predicate Devices:

The Substantial equivalence of this device is based on equivalence in intended use, material, designs, and operational principles to the predicate devices, Maxima™ Anterior Cervical Plate System (K061002) by U&I Coporation and VENTURE™ Anterior Cervical Plate System (K061274) by Medtronic Sofamor Danek.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 31 2012

DIO Medical Company, Limited
% Kodent, Incorporated
Ms. April Lee
325 North Puente Street, Unit B
Brea, California 92821

Re: K121862
Trade/Device Name: Rex Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 15, 2012
Received: October 17, 2012

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K121862

Device Name: RexAnterior Cervical plate system

Indication for Use:

The REX Anterior Cervical Plate System is intended for anterior fixation to the cervical spine. The specific clinical indications include:

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Prescription Use _____x_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121862